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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,214	01/09/2001	Kenji Yamashita	Q62578	4067

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EXAMINER

EWOLDT, GERALD R

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/756,214

Applicant(s)  
Yamashita et al.

Examiner  
G.R. Ewoldt, Ph.D.

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 30, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27 and 29-32 is/are pending in the application.
- 4a) Of the above, claim(s) 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 29, and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/254,170.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

#### DETAILED ACTION

1. Applicant's amendment and remarks, filed 4/30/03, are acknowledged.
2. Claims 27, 29, and 30 are pending and being acted upon.
3. In view of the instant amendment, all previous rejections have been withdrawn. Accordingly, Applicant's arguments have been rendered moot.
4. The substitute specification, filed 1/09/01, has been entered.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:  

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
6. Claims 27, 29, and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U. S. Patent No. 6,171,799 (of record) in view of Schwarz et al. (1995, of record) and Jones et al. (1992).

The '799 patent teaches a culture device for the culturing of immunosuppressive (suppressor) cells, with an affinity for protein, wherein prior to cell culturing the culture device is coated with an anti-CD3 antibody (OKT3) (see particularly column 33, lines 30-53).

The reference differs from the claimed invention in that it does not teach a device further coated with an F(ab)<sub>2</sub> fragment of the anti-CD2 antibody TS2/18 antibody produced by the hybridoma HB195.

Schwarz et al. teaches the culture of T cells with the anti-CD2 TS2/18 antibody and that said culture results in inhibitory effects on T cell activation (see particularly page 5816, column 1, paragraph 4). The reference further teaches that the epitope recognized by TS2/18 is a candidate for CD2-directed

immunosuppression (see particularly page 5817, column 2, paragraph 3).

Jones et al. teaches the interchangeability of whole antibodies and F(ab)<sub>2</sub> fragments for the coating of devices (plastic plates) for the incubation of lymphocytes (see particularly page 236, column 1, second paragraph). The reference further teaches that in some situations an F(ab)<sub>2</sub> fragment is preferable, such as when the reduction of a background signal is desirable, (see Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a culture device for the culturing of immunosuppressive (suppressor) cells, wherein prior to cell culturing the culture device is coated with an anti-CD3 antibody, as taught by the '799 patent, additionally coating the plate with a an anti-CD2 TS2/18 antibody, as taught by the Schwarz et al., employing either the whole antibody or an F(ab)<sub>2</sub> fragment of said antibody, given the fact that whole antibodies and F(ab)<sub>2</sub> fragments are interchangeable and in some situations an F(ab)<sub>2</sub> fragment is preferable, as taught by Jones et al. One of ordinary skill in the art would have been motivated to double-coat (anti-CD2 and anti-CD3) the plate because said double-coating should achieve additional immunosuppression of the immunosuppressive suppressor T cells. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06). Thus, the combination of antibodies would be obvious.

7. Claims 27, 29, and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0421380A1 (1990) in view of Schwarz et al. (1995, of record) and Jones et al. (1992).

EP 0421380A1 teaches a culture device (see particularly page 4, line 16) coated with an anti-CD3 antibody and an anti-CD2 antibody (see particularly page 3, lines 26-27) including an enzymatically cleaved antibody fragments (see particularly page 3, lines 33-36).

The reference differs from the claimed invention in that it does not teach the specific anti-CD2 antibody TS2/18 produced by the hybridoma HB195 nor the use of an F(ab)<sub>2</sub> fragment.

Schwarz et al. teaches the well known anti-CD2 antibody TS2/18 produced by the hybridoma HB195 (see particularly Abstract)).

Jones et al. teaches the interchangeability of whole antibodies and F(ab)<sub>2</sub> fragments for the coating of devices (plastic plates) for the incubation of lymphocytes (see particularly page 236, column 1, second paragraph). The reference further teaches that in some situations an F(ab)<sub>2</sub> fragment is preferable, such as when the reduction of a background signal is desirable, (see Abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a culture device coated with an anti-CD3 antibody and an anti-CD2 antibody, including an enzymatically cleaved fragments of an anti-CD2 antibody as taught by EP 0421380A1, employing the TS2/18 anti-CD2 antibody produced by the hybridoma HB195, as taught by Schwarz et al, because the TS2/18 anti-CD2 antibody was well known and readily available, employing either the whole antibody or an F(ab)<sub>2</sub> fragment of said antibody, given the fact that whole antibodies and F(ab)<sub>2</sub> fragments are interchangeable and in some situations an F(ab)<sub>2</sub> fragment is preferable, as taught by Jones et al.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196 or the Customer Service Center at (703) 308-0198.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).



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Primary Examiner  
Technology Center 1600  
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